REMARKS

Claims 35-49 were pending in the instant application. Claims 37 and 41 have been cancelled. Claims 35, 38, 39, 40 and 42 have been amended, and claim 50 has been added to more specifically point out what Applicants regard as the invention. Support for the amendments to the claims can be found throughout the specification and in the claims as originally filed. Specifically, support for the amendment of claim 35 can be found in the specification, for example, at pages 7-8 and pages 20-21. Support for the amendment of claim 39 can be found in the specification, for example, at page2, lines 7-15, at page 5, lines 1-10, and at page 8, lines 29-37. Support for the amendment of claim 42 can be found in the specification, for example, at page3, lines 24-32, and at page 37, lines 3-12. Support for new claim 50 can be found in the specification, for example, at page 10, lines 1-2, and in Example 2.

No new matter has been added. The foregoing claim amendments and cancellations should in no way be construed as an acquiescence to any of the Examiner's rejections, and have been made solely to expedite the prosecution of the application. Applicants reserve the right to pursue the claims as originally filed in this or a separate application(s).

Attached hereto is a marked-up version of the changes made to the claims by the current amendments. The attached page is captioned "Version With Markings to Show Changes Made". In addition, for the Examiner's convenience, a copy of the claims as pending upon entry of the present amendment, is set forth herein as Appendix A.

Double Patenting

The rejection of claim 38 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 13 of U.S. Patent No. 5,958,671 (the '671 patent) was maintained. Specifically, the Office Action states that "although the conflicting claims are not identical, they are not patentably distinct from each other . . ."

Applicants respectfully disagree. However, in the interest of expediting prosecution, Applicants submit herewith a Terminal Disclaimer over the '671 patent. Accordingly, Applicants respectfully request withdrawal of the double patenting rejection over the '671 patent.

Rejections of Claims 35-49 Under 35 U.S.C. § 112, first paragraph

The rejections of claims 35-49 under 35 U.S.C. §112, first paragraph, were maintained on the ground that "the description is not sufficient to describe the broadly claimed genus of any 'maf family' protein,"and further that:

> "the specification, while being enabling for embodiments wherein the immune response assayed is the effect of the test compound on expression of an interleukin-4 gene and wherein the maf family protein is c-Maf, does not reasonably provide enablement for practicing the claimed invention with any other immune response and with any other maf family proteins. (Office Action at page 5)

In the interest of expediting prosecution, claim 35 has now been amended to specify that the maf family protein comprises a transactivation domain and a basic leucine zipper region, and further that the target DNA is a regulatory sequence of a Th2-associated cytokine gene to which the maf family protein binds. Applicants respectfully submit that the ordinary artisan would be able to practice the invention as presently claimed with a reasonable expectation of success given the teachings of the instant specification. The structural and functional relationship between maf family proteins is set forth in the application, for example, at pages 7-8 and 20-21. One of ordinary skill in the art, presented with these teachings, would be able to readily predict those maf family proteins that can be used in the presently claimed invention. Binding and transactivation assays useful for confirming whether a particular maf protein is capable of binding and transactivating gene expression are described in the application, for example, at pages 36-40 and in the Examples. Further, as of the original filing date, the relationship between cytokine regulation and immune response was well-known in the art, and is described generally in the specification, for example at pages 1-3, and the specific relationship between IL-4 activation and the production of other Th2-associated cytokines is described, for example at page 8, lines 32-37 which states in part, "production of Il-4 can lead to the production of additional Th2-associated cytokines such as Il-5, Il-10 and IL-13."

Accordingly, Applicants respectfully submit that in view of the teachings in the specification, they were in possession of the presently claimed invention at the time of filing. Reconsideration and withdrawal of the rejections of claims 35-49 under 35 U.S.C. § 112, first paragraph, is therefore respectfully requested.

Rejection of claims 35, 37-39 and 41-49 under 35 U.S.C. §112, second paragraph

The rejection of claims 35, 37-39 and 41-49 as being indefinite was maintained on the ground that the metes and bounds of the phrase "a Maf family protein" are unclear.

Applicants respectfully traverse this rejection. As described in the specification, members of the Maf family share common structural and functional features. Specifically, members of the family share a high level of homology (e.g., see page 7, line 35 to page 8, line 4, and page 10 lines 20-35). Members of the Maf family also demonstrate the ability to form homodimers and heterodimers with each other and with Fos and Jun (e.g., see page 8, lines 6-9, and page 20, lines 8-29). Further, in contrast to other AP-1-type proteins, members of the Maf family demonstrate the ability to bind to a specific DNA target sequence, termed the c-Maf response element (MARE) (e.g., see page 8, lines 9-11, and in Examples 3-7). Given these teachings, the metes and bounds of the phrase "a Maf family protein" are clear, and one of ordinary skill in the art would have no trouble determining whether any particular protein belongs to this subfamily of AP-1/CREB/ATF proteins.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 35, 37-39 and 41-49 under 35 U.S.C. § 112, second paragraph.

CONCLUSION

Reconsideration and allowance of all the pending claims is respectfully requested. If a telephone conversation with Applicants' Attorney would expedite prosecution of the above-identified application, the Examiner is urged to call the undersigned at (617) 227-7400.

Respectfully submitted,
LAHIVE & COCKFIELD, LLP

DRAFT

By_____
Cynthia L. Kanik, Ph.D.
Attorney for Applicants
Reg. No. 37,320

LAHIVE & COCKFIELD, LLP
28 State Street
Boston, MA 02109
Tel. (617) 227-7400

Dated:

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the claims:

Claims 37and 41 have been cancelled.

Claims 35, 38, 39, 40 and 42 have been amended.

New claim 50 has been added.

35. **(Amended)** A method for identifying a compound that modulates ~~an immmune response~~ production of a Th2-associated cytokine in a cell, comprising

providing an indicator composition comprising (i) a maf family protein comprising an amino terminal transactivation domain and a carboxy terminal basic leucine zipper region; and (ii) a target DNA comprising a regulatory sequence of a Th2-associated cytokine gene to which said maf family protein binds, wherein said indicator composition ~~being~~ is an indicator cell or an acellular preparation;

contacting the indicator composition with each member of a library of test compounds;

selecting from the library of test compounds a compound of interest that modulates binding of said maf family protein to said target DNA; and

determining the effect of the compound of interest on ~~and immune response~~ the production of a Th2-associated cytokine in a cell to thereby identify a compound that modulates ~~an immune response~~ production of the Th2 cytokine.

38. **(Amended)** The method of claim ~~35~~35, wherein the Th2-associated cytokine gene is an interleukin-4 gene.

39. **(Amended)** The method of claim 35, wherein the effect of the compound of interest on ~~an immune response~~ Th2-associated cytokine production is determined by determining the effect of the compound on development of T helper type 1 (Th1) or T helper type (Th2) cells.

40. **(Amended)** The method of claim 35, wherein the maf family protein is selected from the group consisting of v-maf, ~~mafB, Nrl, mafK, mafG~~ and p18.

42. **(Amended)** The method of claim ~~41~~ 35, wherein the target DNA comprises the regulatory sequence of an interleukin-4 gene.

50. **(New)** The method of claim 44, wherein lymphoid cell is a helper precursor (Thp) cell.

APPENDIX A

35. A method for identifying a compound that modulates production of a Th2-associated cytokine in a cell, comprising

providing an indicator composition comprising (i) a maf family protein comprising an amino terminal transactivation domain and a carboxy terminal basic leucine zipper region; and (ii) a target DNA comprising a regulatory sequence of a Th2-associated cytokine gene to which said maf family protein binds, wherein said indicator composition being an indicator cell or an acellular preparation;

contacting the indicator composition with each member of a library of test compounds;

selecting from the library of test compounds a compound of interest that modulates binding of said maf family protein to said target DNA; and

determining the effect of the compound of interest on the production of a Th2-associated cytokine in a cell to thereby identify a compound that modulates production of the Th2 cytokine.

36. The method of claim 35, wherein the maf family protein is c-Maf.

38. The method of claim 35, wherein the Th2-associated cytokine gene is an interleukin-4 gene.

39. The method of claim 35, wherein the effect of the compound of interest on Th2-associated cytokine production is determined by determining the effect of the compound on development of T helper type 1 (Th1) or T helper type (Th2) cells.

40. The method of claim 35, wherein the maf family protein is selected from the group consisting of v-maf, Nrl and p18.

42. The method of claim 35, wherein the target DNA comprises the regulatory sequence of an interleukin-4 gene.

43. The method of claim 35, wherein the indicator composition is an indicator cell.

44. The method of claim 43, wherein the indicator cell is a lymphoid cell.

45. The method of claim 44, wherein the lymphoid cell is a Th2 cell.

46. The method of claim 44, wherein the lymphoid cell is a Th1 cell.

47. The method of claim 44, wherein the lymphoid cell is a B cell.

48. The method of claim 43, wherein the indicator cell is a non-lymphoid mammalian cell.

49. The method of claim 43, wherein the indicator cell is a yeast cell.

50. The method of claim 44, wherein lymphoid cell is a helper precursor (Thp) cell.